K001716

JUL 1 9 2000

510(k) Summary of Safety and Effectiveness

The following section is included as required by the Safe Medical Device Act (SMDA) of 1990.

Name: pfm Produkte für die Medizin AG
Address: Wankelstr. 60
50996 Cologne
Germany
CONTACT PERSON: Salvadore F. Palomares, RAC

510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:
Trade Name: Redon Set
Common Name: Apparatus, Suction, Single Patient Use, Portable, Non Powered
Classification Name: Same

Equivalent Devices:

Manufacturer:	Snyder Laboratories, Inc.	Manufacturer:	Biomet Inc.
Name:	Snyder Wound Suction Device	Name:	Biomet CWS
510(k) #:	K800542	510(k) #:	K780848A

Device Description:
The Redon Set is a vacuum based suction device for wound drainage purposes. The set comes with a Redon-Drain with pre-connected trocar (leading–needle for drawing the drain from the inside of the wound to the outside of the skin) and a Redon-Bottle (vacuum bottles for suction). Redon Drains are available in 500 mm length with perforations (80 or 150 mm). Redon-Bottles are available in 3 sizes: 200 ml, 400 ml, or 600 ml (each with approximately 50 ml excess reservoir).

The drain is placed inside a wound with the distal ending as deep as possible. The proximal ending of the drain is drawn to the outside of the wound using the pre-connected trocar (drains with pre-connected trocars help to prevent infections when processing multiple wounds). The distance between the wound and the spot where the trocar is drawn out is normally 50 mm. Using sterile scissors cut the trocar. The wound has to be closed by using normal suture. The drain is fixated to the skin with a single suture, preventing accidental removal.

The universal Redon Drain connector is cut to the corresponding size of the drain (measured in Charierre, CH), utilizing sterile scissors. The drain is then connected to the universal Redon connector. Finally the clamp on the rubber fitting of the Redon-bottle has to be opened.

When the green vacuum indicator reaches the position 'min' a change of the bottle is necessary. The healthcare provider replaces the full Redon bottle with a new bottle.

Intended Use:
The Redon Set is a non-powered, single patient, portable suction apparatus that consists of a manually operated plastic disposable evacuation system intended to provide a vacuum for suction drainage of surgical wounds. The Redon Set is used for large wound-areas (i.e., after surgical operations).

Biocompatibility:
The materials used to manufacture the Redon Set are used in legally marketed devices under comparable conditions of use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 9 2000

Pfm Produkte für die Medizin AG
c/o Mr. Salvadore F. Palomares, RAC
154 Via Lampara
Rancho Santa Margarita, California 92688

Re: K001716
Trade Name: Redon Set
Regulatory Class: II
Product Code: JCX
Dated: June 1, 2000
Received: June 5, 2000

Dear Mr. Palomares:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k): K001716

Device Name: **Redon Set**

Indications for Use: The Redon Set is a non-powered, single patient, portable suction apparatus that consists of a manually operated plastic disposable evacuation system intended to provide a vacuum for suction drainage of surgical wounds. The Redon Set is used for large wound-areas (i.e., after surgical operations).

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or _____ Over the Counter Use
(Per 21 CNR 801.109)

Donna R. Bochner

(Division Sign-Off)
Division of ~~Dental, Infection Control, and General Hospital Devices~~ General, Restorative & Neurological Devices
510(k) Number K001716